

# Protecting and Improving the Health of Iowans

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# **COVID-19 Vaccine Information Brief**

July 15, 2022

Changes to the document from the previous version are highlighted in yellow.

## **IMPORTANT/NEW COVID-19 Vaccine Information**

- COVID-19 Vaccine Information Brief Cadence Change
- COVID-19 Vaccine Administration Data
- COVID-19 Vaccine Redistribution
- COMIRNATY Approved for 12 Years of Age and Older
- COVID-19 Vaccine Recommended for Everyone 6 Months and Older
- COVID-19 Vaccine Resources
- Vaccine Dosage: CDC's Recommendation and FDA's Allowances
- COVID 19 Vaccine Interchangeability
- Mixed Series For Children Ages 6 months 4 Years
- Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training
- Moderna COVID-19 Vaccine Upcoming Webinars
- Vaccine Expiration Date Resources
- V-Safe After Vaccination Health Checker

# **COVID-19 Vaccine Information Brief Cadence Change**

The COVID-19 Vaccine Information Brief will be moving to an "as needed" publication moving forward. IDPH remains committed to sharing current updates from CDC and other federal partners regarding COVID-19 vaccine clinical indications, storage and handling changes and additional vaccine resources.

## **COVID-19 Vaccine Administration Data**

**COVID-19** vaccine administration data will transition to the <u>lowa Public Health Tracking Portal</u> in August. The Tracking Portal will include COVID-19 vaccine administration data for individuals 6 months and older. COVID-19 vaccination data will no longer be available in DOMO.

#### **COVID-19 Vaccine Redistribution**

As COVID-19 vaccine doses continue to be purchased by the federal government, the <u>Vaccine Redistribution</u> <u>Policy and Process</u> and <u>Vaccine Redistribution Form</u> are required for each COVID-19 vaccine redistribution. The redistribution of COVID-19 vaccines and the physical transfer of vaccine between COVID-19 vaccination providers MUST ONLY occur after IDPH approval and IRIS transfer is complete.

IDPH will continue to maintain the COVID-19 Vaccine Call Center to support Iowa's healthcare providers. Questions regarding COVID-19 vaccine can be directed to 1-800-831-6293 ext. 1 or COVID19Vaccine@idph.iowa.gov.

# **COMIRNATY Approved for 12 Years of Age and Older**

On July 8, 2022, the FDA approved Pfizer's Biologics License Application, to include individuals 12 through 15 years of age. Previously, Comirnaty could be used in this age group under the EUA. The Biologics License Application, or BLA, is the FDA's standard "full approval" process for biological products. Healthcare providers may continue administering Comirnaty to individuals 12 years of age and older.

#### Resources

- FDA Approval Letter
- Fact Sheet for Recipients and Caregivers Comirnaty, Gray Cap
- Fact Sheet for Healthcare Providers Comirnaty, Gray Cap (No Dilution)

#### **COVID-19 Vaccine Recommended for Everyone 6 Months and Older**

CDC endorsed the Advisory Committee on Immunization Practices' (ACIP) recommendation that all children 6 months through 5 years of age should receive a COVID-19 vaccine. This means all Americans ages 6 months and older are eligible for vaccination. All children, including children who have already had COVID-19, should get vaccinated. COVID-19 vaccines have undergone—and will continue to undergo—the most intensive <u>safety</u> monitoring in U.S. history.



#### **COVID - 19 Vaccine Resources**

COVID-19 clinical materials webpages have been simplified, making materials easier to locate.

#### **Interim Clinical Considerations Resources:**

- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States | CDC
- FAQs for the Interim Clinical Considerations | CDC
- US COVID-19 Vaccine Product Information

#### **Schedule Resources:**

- At-A-Glance Schedule | CDC
- Interim COVID-19 Immunization Schedule | CDC

#### **Vaccine Brand Specific Resources:**

- Moderna COVID-19 Vaccine | CDC
  - Moderna COVID-19 Vaccine At A Glance (cdc.gov)
  - Moderna COVID-19 Vaccine | FDA
  - <u>Vaccine Resource Chart for Healthcare Providers</u>
- Pfizer-BioNTech COVID-19 Vaccines | CDC
  - Pfizer-BioNTech COVID-19 Vaccine At A Glance (cdc.gov).
  - Comirnaty® and Pfizer-BioNTech COVID-19 Vaccine | FDA webpage
  - Vaccine Resource Chart for Healthcare Providers
- Janssen (J&J) COVID-19 Vaccine | CDC
  - Janssen COVID-19 Vaccine | FDA

#### **At-A Glance Product Summary Resources:**

- Moderna COVID-19 Vaccine At A Glance (cdc.gov)
- Pfizer-BioNTech COVID-19 Vaccine At A Glance (cdc.gov)

#### **Infographic Vial Label Resources:**

- Storage, Handling, Preparation, and Administration Job Aids by Product
- Moderna COVID-19 Vaccine Updated label Information 6 Through 11 Years of Age (cdc.gov)
- Pfizer-BioNTech COVID-19 Vaccine Updated label Information 6 Months

#### **At-A-Glance Job Aids Resources:**

- Moderna
- <u>Pfizer</u>

## **Aging Up Resources:**

- Moderna
- Pfizer

#### **Preventing Vaccine Administration Errors Resources:**

- Clinical guidance for errors
- Handout

#### **Community Partners and Vaccine Provider Resources:**

- <u>COVID-19 Vaccination for Children</u>: Up-to-date information and resources to help inform planning and enhance pediatric vaccination
- Quick Conversation Guide: Helps navigate answers to common questions parents and caregivers may have about the COVID-19 vaccines for children and teens
- <u>Vaccinating Children with Disabilities Against COVID-19</u>: Includes strategies to improve COVID-19 vaccine accessibility for children with disabilities and special healthcare needs
- Equity in Childhood COVID-19 Vaccination: Highlights the work currently being done and resources to improve vaccine access and equity

#### Training Materials for Administering Vaccine to Young Children Resources

The CDC has a suite of training materials for administering vaccine to young children. Everything can be accessed from this webpage: <u>Vaccine Administration Resource Library | CDC</u>

#### • Training Guidelines:

- o Training and Education for COVID-19 Vaccination | CDC
- COVID-19 Vaccine: Vaccine Administration Competencies Assessment Form-February 2021 (cdc.gov)

#### Managing Anaphylaxis in People of All Ages:

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html

#### • Printable Job Aids:

- Vaccine Administration: Intramuscular (IM) Injection Infants 11 months of age and younger
- Vaccine Administration: Intramuscular (IM) Injection Children 1 through 2 years of age
- Vaccine Administration: Intramuscular (IM) Injection Children 3 through 6 years of age
- Vaccine Administration: Intramuscular (IM) Injection Children 7 through 18 years of age
- Vaccine Administration: Intramuscular (IM) Injection in Adults 19 years of age and older
- o Vaccine Administration: Needle Gauge and Length

#### **Parents and Caregivers Resources:**

- <u>COVID-19 Vaccines for Children and Teens</u>: website is structured to help parents and caregivers easily find information on important topics, including:
  - o why children and teens should get vaccinated,
  - vaccine safety,
  - o side effects, and
  - preparing for vaccination
- Resources to Promote COVID-19 Vaccination for Children & Teens: Information to help navigate conversations with parents and caregivers

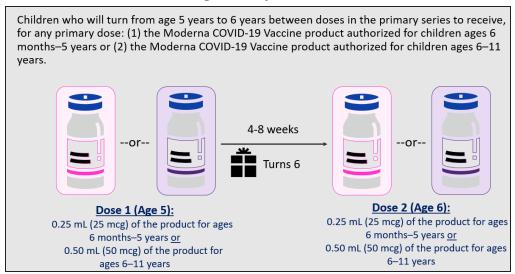
<u>COVID-19 Parent Messaging</u>: The (HHS) COVID-19 Public Education Campaign, "We Can Do This" includes a helpful resource for parents messaging.

## Vaccine Dosage: CDC's Recommendation and FDA's Allowances

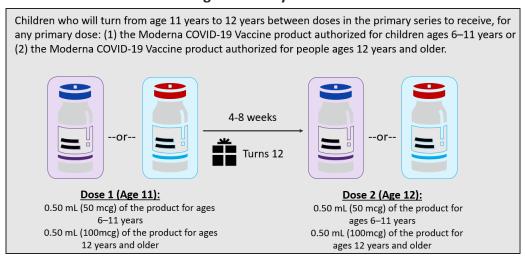
**CDC'S recommendation**: Children should receive the age-appropriate vaccine product and follow the schedule based on their age <u>on the day of vaccination</u>, regardless of their size or weight.

- If a person moves from a younger age group to an older age group during the primary series or between the primary series and receipt of the booster dose(s), they should receive the vaccine dosage for the older age group for all subsequent doses.
  - FDA authorization allows for dosing options for certain age transitions. If these options occur, they are not considered errors and the doses "count".

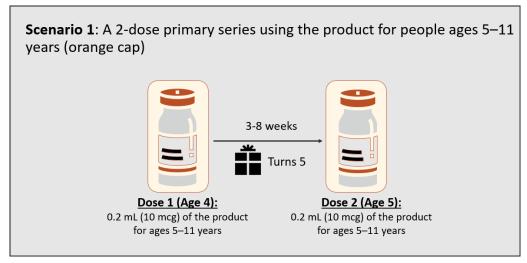
## FDA Allowance for Moderna Age 5 to 6 years



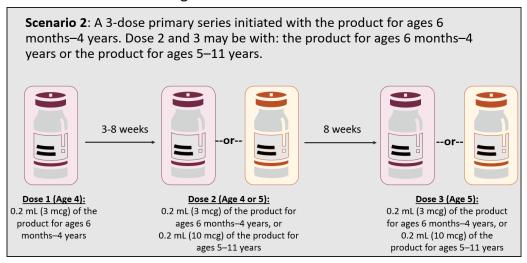
#### FDA Allowance for Moderna Age 11 to 12 years



## FDA Allowance for Pfizer Age 4 to 5 years



## FDA Allowance for Pfizer Age 4 to 5 Years



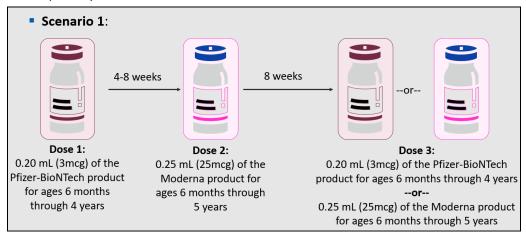
## **COVID-19 Vaccine Interchangeability**

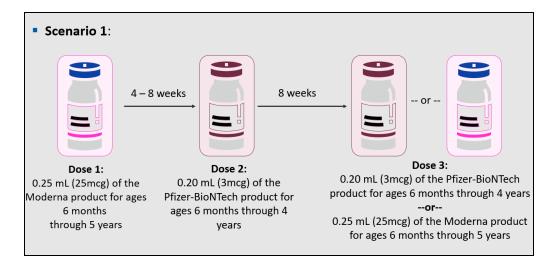
COVID-19 vaccines are not interchangeable. The same mRNA vaccine product should be used for all doses of the primary series.

In exceptional situations in which the mRNA vaccine product administered for a previous dose(s) of the
primary series cannot be determined or is not available, either age-appropriate available mRNA
COVID-19 vaccine product may be administered at a minimum interval of 28 days between doses to
complete the mRNA COVID-19 primary vaccination series.

# Mixed Series For Children Ages 6 months – 4 Years

Children ages 6 months—4 years who receive different mRNA products for the first 2 doses of an mRNA COVID-19 vaccine series should receive a third dose of either mRNA vaccine 8 weeks after the second dose to complete the 3-dose primary series.





## Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training

Pfizer has expanded its training sessions to address questions about currently recommended COVID-19 vaccine products as well as vaccines for children. The COVID-19 vaccine medical updates and site training webinars aim to educate providers and immunization staff on the proper use of the Pfizer-BioNTech COVID-19 Vaccines. For details, see <a href="https://doi.org/d

# **Moderna COVID-19 Vaccine Upcoming Webinars**

Moderna is offering upcoming webinars detailing the pediatric and adolescent indications for the Moderna COVID-19 vaccine. For details, see <u>dates and links for upcoming training sessions</u>.

## Vaccine Expiration Date Resources

Always be sure to check the manufacturer's website to obtain the most up-to-date expiration dates for COVID-19 vaccines. It is important for healthcare providers to update vaccine expiration dates in IRIS. Questions regarding IRIS vaccine inventory and adjusting expirations dates can be directed to the IRIS Helpdesk at 800-374-3958.

For EUA COVID-19 vaccines that do not have a final expiration date, the CDC has set an expiration date of 12/31/2069 to serve as a <u>placeholder date</u>. Such vaccines have a dynamic expiration date, which can change over time as additional stability data become available. This placeholder date, which is far in the future, is intended to serve as a prompt for the provider to check the latest expiry information on the manufacturer's website. It is important for healthcare providers to update vaccine expiration dates in IRIS.

#### The Pfizer COVID-19 vaccine:

## It is important for all healthcare providers to double check all shelf life extensions for all Pfizer products.

Pfizer does not yet have an expiration date look up tool for these vaccines. Pfizer does provide guidance for expiration dates on their <u>website</u>. The date on the label is <u>NOT</u> the expiration date for the <u>ORANGE</u> and <u>GRAY</u> cap vials (not labeled Comirnaty), instead, each vial has the lot number and date of manufacture printed on the label.

As long as approved storage conditions have been maintained, the maroon, orange, gray, and purple cap vaccine vials should not be used after 12 months from the date of manufacture. For vials labeled with a printed expiry date, vaccine vials may be used beyond the printed expiry date as per the table below. Please see the below tables for additional details.



Printed Manufacturing Date	12-Month Expiry Date
01/2022	31-Dec-2022
02/2022	31-Jan-2023
03/2022	28-Feb-2023
04/2022	31-Mar-2023
05/2022	30-Apr-2023
06/2022	31-May-2023



Printed Manufacturing Date	12-Month Expiry Date
07/2021	30-Jun-2022
08/2021	31-Jul-2022
09/2021	31-Aug-2022
10/2021	30-Sep-2022
11/2021	31-0ct-2022
12/2021	30-Nov-2022
01/2022	31-Dec-2022
02/2022	31-Jan-2023
03/2022	28-Feb-2023

<sup>\*</sup>Regardless of storage condition, maroon, orange, and gray cap vaccines should not be used after 12 months from the date of manufacture.



Printed Expiry Date	Updated Expiry Date
12/2021	30-Jun-2022
01/2022	31-Jul-2022
02/2022	31-Aug-2022
03/2022	30-Sept-2022
06/2022	30-Sept-2022
07/2022	31-0ct-2022
08/2022	30-Nov-2022
09/2022	31-Dec-2022
10/2022	31-Jan-2023
11/2022	28-Feb-2023
12/2022	31-Mar-2023



Printed Manufacturing Date	12-Month Expiry Date
07/2021	30-Jun-2022
08/2021	31-Jul-2022
09/2021	31-Aug-2022
10/2021	30-Sep-2022
11/2021	31-0ct-2022
12/2021	30-Nov-2022
01/2022	31-Dec-2022
02/2022	31-Jan-2023

mRNA)-labeled vials  12 years of age and older, DO NOT DILUTE, Gray Cap presentation44		
Printed Expiry Date	Updated Expiry Date	
09/2022	31-Dec-2022	
10/2022	31-Jan-2023	
	ates will be provided er date	

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The vaccine ingredients and formulation contained in all DO NOT DILUTE (Gray Cap) vaccine vials are the same. When prepared according to instructions for use, these can be used interchangeably for vaccinating people ages 12 and older.

References: 1. Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (6 months through 4 years of age), DILUTE BEFORE USE, Maroon Cap. Pfizer and BioNTech; June 17, 2022.

2. Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (5 through 11 years of age), DILUTE BEFORE USE, Orange Cap. Pfizer and BioNTech; June 17, 2022.

3. Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (12 years of age and older), DILUTE BEFORE USE, Purple Cap. Pfizer and BioNTech; June 17, 2022.

4. Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (12 years of age and older), DO NOT DILUTE, Gray Cap. Pfizer and BioNTech; June 17, 2022.

**Janssen COVID-19 vaccine:** The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Call 1-800-565-4008, or
- Go to www.vaxcheck.jnj/

#### Moderna COVID-19 vaccine:

The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Go to www.modernatx.com/covid19vaccine-eua/

CDC's <u>COVID-19 Vaccine Expiration Date Tracking Tool</u> can help providers keep track of the expiration date by lot number.

<sup>\*</sup>Regardless of storage condition, maroon, orange, and gray cap vaccines should not be used after 12 months from the date of manufacture.

Regardless of storage condition, purple cap vaccine should not be used past the 12-month expiry. For vials with expiry dates of October 2021 through March 2022, the printed date on the label/carton reflects 6-month expiry. For vials with expiry dates of June 2022 through December 2022, the printed date on the label/carton reflects 9-month expiry. The vaccine should not be used past the 12-month (updated) expiry date in the table above.

#### V-Safe After Vaccination Health Checker

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after an individual receives a COVID-19 vaccination. V-safe web pages feature information on how to register and complete a v-safe health check-in (including step-by-instructions with images), troubleshooting, FAQs, and contact information for technical support. These web pages will be continuously updated with additional resources.

- V-safe information sheet and poster: Posted on the Vaccine webpage and available in 5 languages: English, Spanish, Korean, Vietnamese, and Simplified Chinese
- Add a dependent and completing their health check-ins
- V-safe after vaccination health checker website
- V-Safe Print Resources
- Vaccine Adverse Event Reporting System (VAERS)